File

Shaunessy No. 105501

Date Out EAB: JAN - 3 1989

TO: G. Werdig
Product Manager 50
Registration Division (TS-767)

FROM: Patrick W. Holden, Chief PWH
Ground-Water Technology Section
EF & GWB/(TS-769C)

THRU: Hank Jacoby, Acting Chief Hank Jacoby
EF & GWB/(TS-769C)

Attached please find the environmental fate review of:

Reg./File No.: _____

Chemical: Tebuthiuron

Type Product: Herbicide

Product Name: _____

Company Name: _____

Submission Purpose: Field Dissipation and Ground Water Monitoring Protocols and meeting summaries

ACTION CODE: 495

Date In: 9-7-88 EAB # 81000 & 90120

Date Completed: 11-24-88 TAIS (level II) Days 2.0

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

Monitoring study requested by EAB: / X /

Monitoring study voluntarily conducted by registrant: /___/

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information — Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME
tebuthirun

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
105501	495	--	5. RECORD NUMBER: 231,145
			6. REFERENCE NUMBER:
			7. DATE RECEIVED (EPA): 8/25/88
			8. STATUTORY DUE DATE: 15 days
			9. PRODUCT MANAGER (PM): S. Hardie/E. Briscoe
			10. PM TEAM NUMBER: 50

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

AH

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS: 9-7-88
12. PRIORITY NUMBER: 29
13. PROJECTED RETURN DATE: 9-21-88

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☐ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD
D. ☐ TSS/RD
E. ☐ Other

F. INSTRUCTIONS

ADVANCE COPY TO EIDEN ON 8/31/88

REVIEW REGISTRANTS CLAIM THAT PROSPECTIVE GROUNDWATER MONITORING STUDY SHOULD BE CONDUCTED INSTEAD OF A SMALL SCALE RETROSPECTIVE MONITORING STUDY AS REQUIRED IN THE ~~COMPRE~~-- Data Call In Notice. Also review proposed protocol

16. RELATED ACTIONS

17. 3(c)(1)(D)
- ☐ Use Any or All Available Information
- ☐ Use Only Attached Data
- ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO
- ☐ TB
- ☐ EEB
- ☐ EF
- ☐ PL
- ☐ RCB
- ☐ EFB
- ☐ CH
- ☐ BFSD

19.	To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY								
		ECOLOGICAL EFFECTS								
		RESIDUE CHEMISTRY								
	XXX	ENVIRONMENTAL DATE Attn.: C. Eiden & M. Barrett								
RD/TSS		CHEMISTRY								
		EFFICACY								
		PRECAUTIONARY LABELING								
BFSD		ECONOMIC ANALYSIS								

20.	21.	22.	23.	24.
☐ Label Submitted with Application Attached	☐ Confidential Statement of Formula	☐ Representative Labels Showing Accepted Uses Attached	Date Returned to RD (to be completed by HED)	Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

EPA Form 8570-13 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE.

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Pack No. 48650
Date Received 11-4-88 EFED

ATTACHMENT 1

OFFICE OF PESTICIDE PROGRAMS DATA REVIEW RECORD

Confidential Business Information Does Not Contain National Security Information(E.O. 12065)
This form is to be used for individual studies and for submission of pesticide applications

1. PRODUCT NAME			CHEMICAL NAME TEBUTHIURON	
2. IDENTIFYING NUMBER	3. RECORD NUMBER	4. ACTION CODE	5. MRID/ACCESSION NUMBER	6. STUDY GUIDELINE OR NARRATIVE
105501	233434	495	n/a	164-1

7. REFERENCE NUMBER	8. DATE RECEIVED (EPA)	9. PRODUCT/REVIEW MANAGER/DCI	10. PM/RM TEAM NUMBER	11. DATE SENT TO (HED/EFED/RD/BEAD)
3	10/18/88	Werdig/Briscoe	50	10/27/88
12. PROJECTED RETURN DATE ~~10-18-88~~ 30 days	13. DATE RETURNED TO (RD/SRRD)	INSTRUCTIONS: Comments on the attached esp. item #2		

(THIS SECTION APPLIES TO REVIEW OF STUDIES ONLY)

14. CHECK APPLICABLE BOX:

15. NUMBER OF INDIVIDUAL STUDIES SUBMITTED ____

☐ ADVERSE 6(a)(2) DATA (405) ☐ GENERIC DATA (660) ☐ PRODUCT SPECIFIC DATA (655)
☐ SPECIAL REVIEW DATA (870) (REREGISTRATION) (REREGISTRATION)

16. HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: yes or no) IF YES, PLEASE IDENTIFY THE STUDY(IES):

17. RELATED ACTIONS:

18.	TO	TYPE OF REVIEW	19. REVIEWS ALSO SENT TO	20. DATA REVIEW CRITERIA
		SCIENCE ANALYSIS & COORD.	SAC	A. Policy Note #31
		TOXICOLOGY/HFA	TOX/HFA	☐ 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
		TOXICOLOGY/IR	TOX/IR	☐ 2 = data of particular concern from registration standard
		DIETARY EXPOSURE	DEB	☐ 3 = data necessary to determine tiered testing requirements
		NON-DIETARY EXPOSURE	NDE	B. Section 18
		ECOLOGICAL EFFECTS	EEB	☐ 1 = data in support of section 3 in lieu of section 18
18	X	ENVIRONMENTAL FATE & GROUND H2O	EFGWB	C. Inert Ingredients
		SPECIAL REVIEW	SR	☐ 1 = data in support of continued use of List 1 inert
		REREGISTRATION	RER	
		GENERIC CHEMICAL SUPPORT	GSC	
		INSECTICIDE-RODENTICIDE	IR	
		FUNGICIDE-HERBICIDE	FH	
		ANTIMICROBIAL	AM	
		PRODUCT CHEMISTRY	PC	
		PRECAUTIONARY LABELING	PL	
		ECONOMIC ANALYSIS	EA	
		ANALYTICAL CHEMISTRY	AC	
		BIOLOGICAL ANALYSIS	BA	

☐ CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS) ☐ LABEL ATTACHED

White - Data Coordinator
Yellow - Data Review Section
Pink - PM/RM/DCI
Green - Return with completed review [illegible] two (2) copies with each submission

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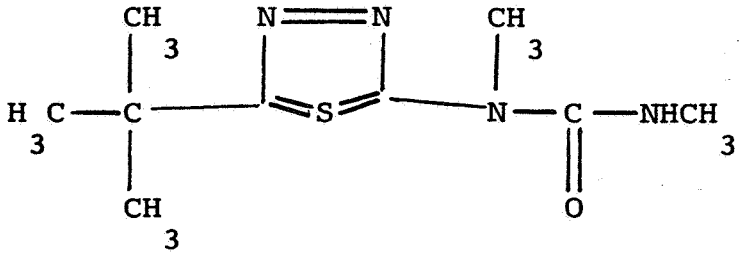
1. Chemical:

Common name: Tebuthiuron

Chemical name: N-(5-(1,1-Dimethyl)-1,3,4-thiadiazol-2-yl)-N,N'-dimethylurea

Structure:



2. Test material:

Not applicable.

3. Study/Action Type:

This action contianed two submissions, including two protocols and two meeting summaries.

The registrant for tebuthiuron (Elanco) has been required to conduct a ground-water monitoring study; a small-scale retrospective study was recommended. On September 13, 1988, Elanco met with RD and EFGWB to discuss the ground-water monitoring requirement for tebuthiuron.

Elanco has requested permission to conduct a small-scale prospective ground-water monitoring study instead of the retrospective, and to use the prospective study as one of the field dissipation studies required in the Registration Standard for tebuthiuron. They want to conduct the small-scale prospective study to simultaneously fulfill the ground-water monitoring study requirement and one of the three field dissipation study requirements outlined in the Registration Standard. They believe a small-scale retrospective study is not appropriate, because tebuthiuron is used in a limited number of situations and infrequently.

After discussions with EFGWB, the registrant decided to reconsider conducting the small-scale prospective study. EFGWB clearly stated, if the registrant opted to conduct a small-scale prospective at this time, a small-scale retrospective study may be required in the future depending on the results of the prospective study.

Under the Conclusion section, the protocols submitted are discussed as to their inadequacies.

4. Study Identification:

"Tebuthiuron Data Call-In Notice for Small-Scale Retrospective Groundwater Monitoring Study (EPA REG. No. 1471-101) 90-Day Response to Notice. Request for Conference. (letter dated 8/25/88). Addenda A, B, and C. Proposed Plan and Study Design for the Small-Scale Prospective Ground Water and Field Dissipation Studies". Record number 231, 145. No accession no.

Letter dated 10/12/88 from Merlyn L. Jones to Geri Werdig discussing a meeting held on 9/13/88 with EFGWB and RD. No accession no. Record no. 233,934.

5. Reviewed by:

Catherine Eiden, Chemist
Ground-Water Technology Section
EFGWB

Catherine Eiden
11/24/88

6. Approved by:

Patrick W. Holden, Chief
Ground-Water Technology Section
EFGWB

Patrick W. Holden
12/27/88

7. Conclusion:

1. The registrant must determine within 90 days which type of ground-water monitoring study they will conduct, either small-scale prospective or retrospective.

2. If they choose to conduct the prospective ground-water study, they must identify possible study site(s) and collect the data needed to select a final site. Specifically, they must choose a worst-case site with no prior use of tebuthiuron. The site must be worst-case with regards to the potential of tebuthiuron to leach at that site. Any site must be discussed and agreed upon by the Agency and Elanco, before final approval. In general, the site must have a permeable soil (sandy loam or loamy sand) with a low percentage of organic matter, a slope less than 2 %, a depth to the water table of less than 30 feet, and no restrictive layers between the land surface and the water table.

The following general points apply to the prospective study:

The study must include suction-lysimeters.

A broadcast application is appropriate for the study.

If the prospective study indicates movement to the shallow ground water, a small-scale retrospective study may be required. Movement to the shallow ground water may be indicated from detections of tebuthiuron/degradates in suction-lysimeter samples or in the ground water.

Analysis of the degradate 104 is adequate. The minimum detection limits (MDLs) for tebuthiuron in soils and water are adequate. Will these same MDLs be used for the degradate?

3. If they choose to conduct the retrospective ground-water monitoring study, they must provide the Agency with sales information on a county basis for tebuthiuron. Based upon the usage information, the registrant should select several counties with high to moderate use of tebuthiuron representing the different uses of tebuthiuron, i.e., a high use county where tebuthiuron is used for total vegetation control (TVC) in Texas along a right-of-way; a high use county where tebuthiuron is used to control rangeland brush, etc. Within these counties, they must identify possible sites as study sites using the following criteria:

Sites with depths to ground water of less than 30 feet.

Sites with slopes less than 2%.

Sites with no restrictive layers between the water table and the land surface.

Sites with a documented history of tebuthiuron use (i.e., a site with a 5 to 10 year use history detailing frequency of use at the site).

The site(s) must be part of an ongoing agricultural operation, that is, not isolated research site(s).

If irrigation is a normal practice for the particular use of tebuthiuron, it must be included in the study design and available at the study site(s).

4. The two protocols submitted for the field dissipation and ground water monitoring studies are not adequate. Each is discussed below as to what is necessary to make them adequate.

A. The protocol submitted for the small-scale prospective ground-water monitoring study is not fully adequate. The following points must be included in the final study design before the Agency will approve it:

The study must include suction lysimeters.

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The soil samples must be collected as 15 cores/ depth/ sampling interval. These may be composited to some small number of composites for analysis, greater than or equal to 3 composites is recommended.

Irrigation must be available at the site to ensure 100% of a 10 year average rainfall for the selected site.

There is no need to establish a band of residue free soil 2 feet wide beneath the deepest point of detected residue in the soil. Sampling to three feet throughout the study until the half-life of the parent and the pattern of formation and decline of the degradate(s) are determined will be adequate. Past the three depth, suction lysimeters will be used to track any deeper movement of tebuthiuron and its degradates. as discussed in the draft "Guidance Document for Ground-Water Monitoring Studies", the suction-lysimeters should be placed at approximately 3, 6, 9 feet in clusters. More than one cluster is recommended to ensure enough sample volume for analysis from a given depth.

B. The protocol submitted for the field dissipation study was not fully adequate. The following points must be included in this protocol before it is adequate:

The soil samples must be collected as 15 cores/ depth/ sampling interval. These may be composited to some small number of composites for analysis, greater than or equal to 3 composites is recommended.

Irrigation must be available at the site to ensure 100% of a 10 year average rainfall for the selected site.

There is no need to establish a band of residue free soil 2 feet wide beneath the deepest point of detected residue in the soil. Sampling to three feet throughout the study until the half-life of the parent and the pattern of formation and decline of the degradate(s) are determined will be adequate.

The sites chosen in Nebraska and California must be described as to the soil types and typical agricultural practices for tebuthiuron.

8. Recommendations:

After Elanco has determined which study to conduct within 90 days, EFGWB, RD and Elanco will meet again to select the sites for either a small-scale prospective or retrospective ground-water monitoring study. All points outlined in this review under the Conclusion section must be incorporated into the protocols submitted for their final approval.

9. Background:

For total control of vegetation woody plants in noncropland areas. Also for brush and weed control in rangeland.

10. Discussion of Individual Studies:

A. Study Identification:

"Addendum A: Proposed Plan/Study Design (Small-Scale Prospective and Field Dissipation Studies)". Record No. 231, 145. J.D. Helmer.

B. Materials and Methods:

The protocol for the small-scale prospective monitoring study is described:

Site Selection

The registrant will seek a site with no prior usage of tebuthiuron, a water table less than 30 feet, a surface slope of less than 2%, no confining layers between the soil surface and the water table, and irrigation must be available at the site to ensure adequate rainfall.

Well Construction

They will construct wells, 3 clusters of 2-3 wells each penetrating the water table aquifer at 5, 10, and 15 feet, respectively.

Soil and Water Sampling

Soils will be sampled to the water table for characterization, and the local ground water flow will be determined. Soil cores will be taken at 0, 14 da s and 1, 2, 3, 6, 9, 12, 15, 18, 21, 24, 30, 36, 42, 48, 54, and 60 months. Soil grids will be measured off on the field and samples will be taken in 6 inch increments to 24 inches, then in 1 foot increments between 2 and 4 feet. Additional soil samples will be taken if necessary to define the depth of leaching. The registrant intends to take 8 soil cores per sampling depth and interval. All cores will be analyzed individually at the 0-6 and 6-12 inch depths. Deeper samples will be composited to 2 composites for analysis.

Water samples will be collected from wells at pretreatment, 14 days and monthly for 24 months, then quarterly for a total of 5 years of sampling. Well sampling procedures will adhere as closely as possible to the guidance outlined in the draft "Guidance Document for Ground-Water Monitoring Studies".

The minimum detection limits (MDLs) are as follows: 30 ppb for the 0-6 and 6-12 inch soil increments for tebuthiuron; 10 ppb for deeper soil increments for tebuthiuron; and 1 ppb for well water

analyzed for tebuthiuron. The major metabolite, (N-[5-(1,1 dimethyl ethyl)-1, 3, 4-thiadiazol-2-yl]-N-methylurea will be analyzed along with the parent. Detection limits for the metabolite were not specified.

C/D. Reported Results and Conclusions:

Not applicable at this time.

E. Reviewer's Conclusions:

The protocol submitted here is inadequate for a small-scale prospective study design. Please refer back to the Conclusions section of this review for details. The field dissipation protocol submitted was very similar to that protocol described above for the small-scale prospective study and will not be detailed here. The field dissipation protocol is inadequate; please refer to the Conclusions section of this review for the details.

11. One-Liner:

Not applicable.

12. CBI:

No CBI were submitted with this submission.